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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/537,416 | 03/29/2000 | Yoshiki Takashima | Q58481 | 6832 |

7590

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EXAMINER

SAUCIER, SANDRA E

ART UNIT PAPER NUMBER

1651

DATE MAILED: 12/04/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/537,416

Applicant(s)

Takashima et al.

Examiner

Sandra Saucier

Art Unit

1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 27, 2001
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8, and 9 is/are rejected.
- 7) ☒ Claim(s) 6 and 7 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Claims 1-9 are pending and are considered on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 1, 2, 5, 8 and 9 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 4,510,246 [A].

The claims are directed to a process of converting an enantiomer of an amino acid of formula 1 to the opposite enantiomer using a biological material which is not inhibited by the claim specific amino acid transferase inhibitors.

US 4,510,246 discloses the use of epimerase obtained from *Streptomyces clavuligerus*, *cattleya* or *lipmanii* to epimerize isopenicillin N to penicillin N (col. 4, l. 1-10).

Claims 1, 2, 5, 8 and 9 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Laiz *et al.* (IDS).

Laiz *et al.* disclose an epimerase obtained from *Nocardia lactamdurans* or *Streptomyces clavuligerus* and its use to epimerize isopenicillin N.

Response to Arguments

Applicants argue that the epimerase disclosed in '246 or Laiz *et al.* does not convert one enantiomer of penicillin into the other, but converts one enantiomer into a racemic mixture. While this may be true, i.e., the instant claims do not have any optical purity limitations. When one converts an optically pure isomer 1 into a mixture of isomers 1 and 2, at least some of isomer 1 has been converted into isomer 2. This is all that the claims require. Thus, the argument is unpersuasive and does not overcome the rejection.

Claim Rejections - 35 USC § 102/103

Claims 1-3, 5, 8 and 9 remain rejected under 35 U.S.C. 102(b) as being anticipated by or obvious under 35 U.S.C. 103 over Lim *et al.* [U] in light of the teachings of ATCC Catalog of Bacteria [V].

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The claims are directed to a process of converting an enantiomer of an amino acid of formula 1 to the opposite enantiomer using a biological material which is not inhibited by the claim specific amino acid transferase inhibitors.

Lim *et al.* disclose a racemase isolated from *Pseudomonas putida* which acts on the substrates of Table 3 as well as both L and D-threonine.

Since microbes from the genus "*Flavimonas*" have been classified in the past by those of skill in the art as *Pseudomonas*, page 168 ATCC Catalog of Bacteria, use of microbes from genus *Flavimonas* is considered to be the same or obvious over the use of microbes from the genus *Pseudomonas*.

Response to Arguments

Applicants argue that Lim *et al.* does not use the same enzyme as they do to effect inversion of the chirality of the α -carbon of an amino acid. While this may be true, the claims do not require the use of any specific enzyme, merely that some isomer 1 be converted to isomer 2. The reference fulfills the claimed method.

Claim Rejections - 35 USC § 103

Claims 1-3, 8 and 9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Gosling *et al.* [W] or Hashimoto *et al.* [X].

The claims are directed to a process of converting an enantiomer of an amino acid of formula 1 to the opposite enantiomer using a biological material which is not inhibited by the claim specific amino acid transferase inhibitors.

The references are relied upon as explained below.

Gosling *et al.* disclose that a microbe from *Rhizobium* possesses an alanine racemase.

Hashimoto *et al.*, deduce that a microbe from *Arthrobacter* has D-alanine racemase activity.

Although the above references do not specifically demonstrate or isolate the racemase activity from the above genera, the named activity strongly suggests that one of skill in the art to use it to catalyze the racemization of

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alanine from either D or L alanine or a none racemic mixture of the two isomers.

Response to Arguments

Applicants argue that the references disclose use of an enzyme which converts one optical isomer into a racemic mixture, while their process converts one isomer into another. While this may be true, please note that no purity limitations are present in the claims, which only require the conversion of one molecule of one isomer into one molecule of the other isomer.

Allowable Subject Matter

Claims directed to the conversion of D-amino acids to L-amino acids or a mixture of D,L-amino acids to L-amino acids of formula (1) using the microbes of the genus/species of claim 6 and the strains of claim 7 appear to be free of the art at this time.

Claims 6 and 7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30AM to 6:00PM Tuesday-Friday and

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every other Monday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of papers is (703) 308-2742 or (703) 305-3592.

A handwritten signature in black ink, appearing to read 'Sandra Saucier', with a long horizontal flourish extending to the right.

Sandra Saucier
Primary Examiner
Art Unit 1651
November 20, 2001